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Case Docket No. NIH297.1C1C1C1

Date: July 7, 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) :

Carlton et al.

Appl. No.

10/659,698

Filed

September 11, 2003

For

ANTIBACTERIAL THERAPY

WITH BACTERIOPHAGE PHYSICO-CHEMICALLY ALTERED TO DELAY INACTIVATION BY THE HOST DEFENSE SYSTEM

Examiner

Unknown

Group Art Unit:

1645

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop: Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

July 7, 2004

Date)

Nancy W. Vensko, Reg. No. 36,298

TRANSMITTAL LETTER

Mail Stop: Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing in the above-identified application are:

- (X) An Information Disclosure Statement.
- (X) A PTO Form 1449 with forty-seven (47) references.
- (X) The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 11-1410.
- (X) Return prepaid postcard.

Mancy W. Vensko

Registration No. 36,298

Attorney of Record

Customer No. 20,995

(805) 547-5580

INFORMATION DISCLOSURE STATEMENT

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Examiner

Unknown

Group Art Unit

1645

Mail Stop: Amendment Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

Enclosed is form PTO-1449 listing 47 references. Copies of disclosed U.S. patents and/or publications are not included pursuant to PTO waiver of the requirement under 37 C.F.R. § 1.98(a)(2)(i) for applications filed after June 30, 2003. Copies of other references, if listed, are enclosed.

This Information Disclosure Statement is being filed before the receipt of a first Office Action on the merits, and presumably no fee is required in accordance with 37 C.F.R. § 1.97(b)(3). If a first Office Action on the merits was mailed before the mailing date of this Statement, the Commissioner is authorized to charge the fee set forth in 37 C.F.R. § 1.17(p) to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 7/7/04/

By: Nancy W. Vensko

Registration No. 36,298

Attorney of Record

Customer No. 20,995

(805) 547-5580

FORM I	PTO-1449
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U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY.	DOCK	ET NO.
NIH2	97.1C1	C1C1

APPLICATION NO. 10/659,698

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

APPLICANT Carlton et al.

SEVERAL SHEETS IF NECESSARY)

FILING DATE September 11, 2003 GROUP 1645

U.S. PATENT DOCUMENTS

COMMOD	AV .	13.1		<u> </u>		, ,	
EXAMINER INITIAL		DOCUMENT NUMBER	DATE .	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)
	1	4,332,897	06/01/1982	Nakano et al.			
	2	4,375,734	03/08/1983	Kozloff et al.			
	3	4,797,363	01/10/1989	Teodorescu et al.			
	4	4,865,979	09/12/1989	Nakano et al.			
	5	4,946,778	08/07/1990	Ladner et al.			
	6	5,132,221	06/21/1992	Ward et al.			
	7	5,168,037	12/01/1992	Entis et al.			
.	8	5,284,934	02/08/1994	Allen, Jr.			
	9	5,344,822	09/06/1994	Levine et al.			

			FOREIGN PATENT DOCUMENTS				
EXAMINER	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANS	LATION
INITIAL						YES	NO

EXAMINER INITIAL		OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)				
		Angel, M.F. et al. 1987 "Beneficial effects of staphage lysate in the treatment of chronic recurrent hidradenitis suppurativa," Surgical Forum 38:111-112.				
	11	Audesirk, G. et al. 1986 Biology Life on Earth, Macmillan Publishing Company, N.Y. pp. 202-203.				
	12	Bendinelli, M. et al. 1988 "Disruption of Phagosomal Membrane by the Virulent H37Rv Strain of <i>M. tuberculosis</i> " in: Mycobacterium tuberculosis: Interactions With the Immune System (Infectious Agents and Pathogenesis), Herman Friedman (Editor), Plenum Press, pp. 311-313.				
		Berchieri, A. Jr. et al. 1991 "The activity in the chicken alimentary tract of bacteriophages lytic for Salmonella typhimurium," Res. Microbiol. 142:541-549.				
		Bogovazova, G.G. et al. 1992 "Immunobiological properties and therapeutic effectiveness of Klebsiella bacteriophages preparations," Zh. Mikrobiol. Epidemiol. Immunobiol. 3:30-33.				
	15	Cislo, M. et al. 1987 "Bacteriophage treatment of suppurative skin infections." Arch Immunol Ther Exp (Warsz). 35:175-183.				
	16	Engelstad, M. et al. 1992 "A constitutively expressed vaccinia gene encodes a 42-kDa glycoprotein related to complement control factors that forms part of the extracellular virus envelope." Virology 188:801-810.				
	17	Frank, M.M. et al. 1992 "The Mechanism by which microorganisms avoid complement attack," Curr. Opin. Immunol. 4:14-19.				
	18	Geier, M.R. et al. 1973 "Fate of bacteriophage Lamda in non-immune germ-free mice," Nature 246:221-222.				

EXAMINER		DATE CONSIDERED	

*EXAMINER: INITIAL IF CITATION CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP 609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED, INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

•	FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY, DOCKET NO. NIH297.1C1C1C1	APPLICATION NO. 10/659,698	
		DISCLOSURE STATEMENT Y APPLICANT	APPLICANT		
	(USE SEVERA	L SHEETS IF NECESSARY)	Carlton et al. FILING DATE September 11, 2003	GROUP 1645	

EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)							
	19	Gherna, R., et al. 1992 American Type Culture Collection Catalogue of Bacteria and Phages, Eighteenth edition, pp. 402-409.						
	20	Hidaka, Y. et al. 1991 "Glycoprotein C of herpes simplex virus type 1 is essential for the virus to evade antibody-independent complement-mediated virus inactivation and lysis of virus-infected cells" <i>J. Gen. Virol.</i> 72:915-921.						
	21	Isaacs, S.N. et al. 1992 "Characterization of a vaccinia virus-encoded 42-kilodalton class I membrane glycoprotein component of the extracellular virus envelope" <i>J. Virol.</i> 66 :7217-7224.						
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	23	Jackson, R.J. et al. 2001 "Expression of mouse interleukin-4 by a recombinant ectromelia virus suppresses cytolytic lymphocyte responses and overcomes genetic resistance to mousepox," <i>J. Virol.</i> 75 :1205-1210.						
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	26	Lambris, J.D. et al. 1993 "Use of synthetic peptides in exploring and modifying complement reactivities." In <u>Activators and inhibitors of complement activation</u> . R.B. Sim, editor. Kluwer Academic Press, Lancaster. pp. 201-232.						
	27	Mazacek, M. et al. 1969 "Die Bakteriophagie in der therapie und prophylaxe der infektionskrankheiten," Zentralbl. Bakteriol. 211:385-394.						
	28	Merril, C.R. et al. (1996) "Long-circulating bacteriophage as antibacterial agents," PNAS USA 93:3188-3192.						
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	30	Peake, P. et al. 1990 "Peptide inhibitors of C3 breakdown." Clin. Exp. Immunol. 79:454-458.						
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	33	Rother, R.P. et al. 1995 "Protection of retroviral vector particles in human blood through complement inhibition." Human Gene Therapy 6:429-435.						
-	34	Salmon, G.G. Jr. et al. 1963 "Staphage lysate therapy in chronic staphylccoccal infections," J. Med. Soc. N. J. 60:188-193.						
	35	Schasteen, C.S. et al., 1988 "Synthetic peptide inhibitors of complement serine proteasesII. Effects on hemolytic activity and production of C3a and C4a." <i>Molec. Immunol.</i> 25:1269-1275.						
	36	Slopek, S. et al. 1983 "Results of bacteriophage treatment of suppurative bacterial infections. I. General evaluation of the results." <i>Arch Immunol Ther Exp (Warsz)</i> 31:267-291.						
	37	Slopek, S. et al. 1983 "Results of bacteriophage treatment of suppurative bacterial infections. II. Detailed evaluation of the results." <i>Arch Immunol Ther Exp (Warsz)</i> 31:293-297.						
	38	Slopek, S. et al. 1984 "Results of bacteriophage treatment of suppurative bacterial infections. III. Detailed evaluation of the results obtained in further 150 cases." <i>Arch Immunol Ther Exp (Warsz)</i> 32 :317-335.						
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EXAMINER	DATE CONSIDERED
ASYANDED INITIAL IS CITATION CONCIDEDED MILETUED OF NOT CITATION	IS IN CONFORMANCE WITH MPER 609: DRAW LINE THROUGH CITATION IF NOT

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•	FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY, DOCKET NO. NIH297.1C1C1C1	APPLICATION NO. 10/659,698
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			FILING DATE September 11, 2003	GROUP 1645

EXAMINER INITIAL		OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
	40	Slopek, S. et al. 1985 "Results of bacteriophage treatment of suppurative bacterial infections. VI. Analysis of treatment of suppurative staphylococcal infections," <i>Arch Immunol Ther Exp (Warsz)</i> 33:261-273.
	41	Smith, H.W. et al. 1982 "Successful treatment of experimental <i>Escherichia coli</i> infections in mice using phage: its general superiority over antibiotics," <i>J. Gen. Microbiol.</i> 128:307-318.
	42	Smith, H.W. et al. 1983 "Effectiveness of phages in treating experimental Escherichia coli diarrhea in calves, piglets and lambs," J. Gen. Microbiol. 129:2659-2675.
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	44	Soothill, J.S. 1992 "Treatment of experimental infections of mice with bacteriophages," J. Med. Microbiol. 37:258-261.
	45	Stent, G. 1963 "The Twort-D'Herelle Phenomenon," in: Molecular Biology of Bacterial Viruses, W.H. Freeman and Co., San Francisco and London, Chapter 1, pp. 1-21.
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DATE CONSIDERED